REMARKS

Claims 2-7, 9 and 11-51 are currently pending in the application. Claim 2 is canceled. Claims 3, 4, 11 and 50 are amended.

The amendments find support in the specification. Specifically, myocardial implants are described throughout the specification, and configuration of the implants to resist migration is supported by claim 1 as originally filed. Implants having a flexible body with proximal and distal portions and the proximal portion prior to implantation having a larger profile than the distal portion is supported throughout the specification and by claim 2 as originally filed. Implants having a tail are supported throughout the specification and by claim 4 as originally filed. No new matter is added.

Information Disclosure Statement

An Information Disclosure Statement (IDS) was filed on January 13, 2004. Entry of the IDS is respectfully requested.

Claim Rejections Under 35 U.S.C. § 102

Claims 2-3, 11-12, 20-21, 34-35 and 50 are rejected under 35 U.S.C. § 102(b) as being anticipated by Neuss (U.S. Pat. No. 5,536,274). Neuss discloses removable or repositionable occlusive implants (column 1, lines 10-12, 40-44, 60-67; column 2, lines 1-6) to be implanted in an "organ pathway", preferably a blood vessel. No myocardial implants are disclosed, nor is there any suggestion that the devices can be implanted in the myocardium. Neuss does not teach or suggest implants having a tail, and therefore does not anticipate applicants' claims. Neuss also does not teach or disclose a surgical adhesive applied to the device. Column 4, lines 23-40 discuss applying heparin to the device to prevent thrombosis after the device is implanted. Heparin is not a surgical adhesive. Neuss also does not teach or suggest a device where the coils of the distal portion define a constant diameter and the coils of the proximal portion define at increasing diameter. Fig. 5 of Neuss shows a device where the coils progressively increase in diameter from one end to the other.

Because Neuss does not teach the subject matter of applicants' claims, applicants respectfully request that the rejection on this basis be reconsidered and withdrawn.

Claim 49 is rejected under 35 U.S.C. § 102(a) as being anticipated by Hussein *et al.* (U.S. Pat. No. 5,810,836). Hussein discloses a flexible stent in the shape of a coil. There is no suggestion that the implant can be larger in profile at one end relative to the other end. There is also no suggestion that the device have sufficient longitudinal flexibility to absorb migratory forces that the local tissue may apply to the device after implantation.

The rejection on this basis should be reconsidered and withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claims 4-7, 18-19, 22-24 and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Neuss in view of Barnhart (U.S. Pat. No. 5,893,869) ("Barnhart"). The office action relies upon the Barnhart reference to supply the "tail" recited in applicants' claims.

Barnhart discloses a blood filter, which is implanted in the vena cava. applicants' claims, in contrast, describe a device to be implanted in the myocardium. The Barnhart device has a loop at its distal end which creates a blunt surface so that the distal end does not snag, erode or perforate the vena cava (column 4, lines 21-26; column 5, lines 63-66). Placement of the Barnhart device in the vena cava is shown in Fig. 5. Both the Neuss and the Barnhart references state that the devices are to be implanted in blood vessels -- the Neuss vessel occlusion devices are intended to be "for organ pathways, preferably for blood vessels" (column 1, lines 3-9), while the Barnhart devices are stated as being vena cava filters (column 1, lines 6-8). There is no teaching or suggestion in either of these references that it would be desirable or even possible to implant the cited devices in solid tissue.

Furthermore, the combination of the Neuss and Barnhart references does not produce the claimed invention. Rather, the combination of Neuss and Barnhart would result in a device to be implanted in a blood vessel (Neuss, Barnhart), where the device was constructed of either a tube (Neuss), or of a spirally wound wire which was in turn wound into a secondary spiral (Neuss), where the spiral windings of the device increased in circumference (Neuss, Barnhart), and then ended in a small loop (Barnart). One of ordinary skill in the art would not view a myocardial implant device configured to resist migration as an obvious extension of what is taught in Neuss and Barnhart.

Applicants also respectfully submit that the office action has supplied no motivation to combine these references, and that the rejection based on the combination of these two references reflects an impermissible hindsight reconstruction of applicants' device.

For example, the office action states that Barnhart discloses a device having a tail defining a profile that is larger than the distal portion of the body (Fig. 1, part 27). This is not true. The tail of the Barnhart device (part 27) is much smaller than any of the coils of the device as shown. The office action also states that the tail of the Barnhart blood filter is configured to remain at the tissue surface when the device is implanted. However, there is no teaching or suggestion that the filter is configured in this way, and Fig. 5 of Barnhart shows the entire filter implanted in the vena cava. The tail of the Barnhart filter is also not formed by a more broadly wrapped coil adjacent to the body, forming an arm that extends laterally away from body of the spring, as is stated in the office action. Instead, the tail is a very small loop at the distal end of the device, and does not extend laterally away from the body of the device. Indeed, if the end of the Barnhart filter were configured as is stated in applicants' claims, the end of the device would be likely to "snag, erode or perforate the vena cava". Barnhart therefore teaches away from applicants' device.

The Federal Circuit has stated that "[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching[,] suggestion or incentive supporting the combination" (*In re Geiger*, 815 F.2d 686, 688, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987)) and that "[i]t is impermissible . . . simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. . . . The references themselves must provide some teaching whereby the applicant's combination would have been obvious." (*In re Gorman*, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991)).

Applicants respectfully submit that the statements that it would have been "obvious" to incorporate a tail that is larger than the distal portion of the body of the device, or a tail that forms an arm that extends laterally away, etc., are impermissible hindsight reconstruction, and show that the specification has been used as a "road map" to re-assemble applicants' claimed invention. "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art

to defeat patentability -- the essence of hindsight." *In re Dembiczak* (50 U.S.P.Q.2d 1614 (Fed. Cir. 1999)). Applicants therefore respectfully request that the rejection on this basis be reconsidered and withdrawn.

Claims 9, 13-15, 36-37 and 51 are also rejected under 35 U.S.C. § 103(a) as being unpatentable over Neuss alone, the office action stating that "[i]t is inherent" that the device of Neuss "may be configured to resist migration by exhibiting longitudinal flexibility to substantially absorb migratory forces" (office action, page 6). However, a rejection based on inherency must be made under 35 U.S.C. § 102, and must establish a prima facie case of anticipation of the claimed subject matter ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." (*PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 37 U.S.P.Q.2d 1618, 1624 (Fed. Cir. 1996), citing *Chester v. Miller*, 906 F.2d 1574, 1576 n.2, 15 U.S.P.Q.2d 1333, 1336 n.2 (Fed. Cir. 1990), *In re Donohue*, 766 F.2d 531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985))). The MPEP discusses inherency at § 2112, and in what circumstances such a rejection can be made:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) . . . ; *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

(emphasis added).

In the present case, not only has the office action failed to establish that the necessary characteristics of applicants' devices are necessarily present in the vessel occlusion devices of Neuss, the office action merely states that applicants' devices are inherent in the Neuss reference because the Neuss devices "may" be configured to resist migration. The office action therefore fails to establish a rejection based on the principle of inherency.

Furthermore, there is no teaching or suggestion in either Neuss of Bernhart that the cited devices could be configured to resist migration, especially in as rigorous an environment as the myocardium. The cited references contain no statements that the devices can be used or modified for implantation in the myocardium. In fact, the references completely fail to address the possible migration of the devices in blood vessels. A critical aspect of the claimed invention, that the implant be configured to resist migration after being placed within the myocardium, is therefore missing, and the rejection must be reconsidered and withdrawn.

Claims 16-17 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Neuss and Cottenceau *et al.* (U.S. Pat. No. 5,484,424; "Cottonceau"). The office action appears to rely on Cottonceau to provide a spring of varying flexibility.

However, the Cottonceau reference discloses a catheter with a blood filter attached to one end. Springs are illustrated in Figs. 13 and 14 and are clearly stated (at the cited portions of column 5, lines 25-26) to be springs intended to be incorporated into the walls of the catheter to stiffen it. The springs illustrated in Cottonceau therefore do not exist outside of the catheter, and this reference is therefore not relevant to applicants' myocardial implants. The rejection on this basis must be withdrawn.

Claims 25-29 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Neuss, Barnhart and Whalen (U.S. Pat. No. 4,130,904; "Whalen"). Whalen discloses a prosthetic blood conduit, made of a coil spring sandwiched between two polyester fabric tubes. The office action points to Fig. 2 of Whalen as supplying the joining of the end of the wire making up the coil to a loop of the coil, either by welding or by means of a malleable sleeve.

There is no suggestion or motivation to combine the cited references in this way. Whalen discloses a synthetic blood vessel, while Neuss and Barnhart disclose an implant for organ pathways and a blood filter, respectively. There is no teaching or suggestion in any of these references that portions of the Whalen device (the polyester tubes covering the coil) be subtracted, and that one small element of the device be combined with portions of a vessel occlusion device and a blood filter. The references are from disparate fields, and there is no

reason to believe (and none given in the office action) that a person of ordinary skill in the field of myocardial implants would have any motivation or see any benefit to combining these references in this way. Again, applicants respectfully submit that the claimed invention has been used as a road map for combining the references, which is impermissible in establishing a rejection based on obviousness. Applicants therefore ask that the that the rejection on this basis be reconsidered and withdrawn.

Claims 31-33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Neuss, Barnhart, Whalen and Hussein. The office action relies on Hussein to provide a neck portion comprising a straight line segment that lies in a plane substantially parallel to the longitudinal axis of the device, as is recited in claims 32 and 33.

However, a dependent claim includes all of the limitations of the claims from which it depends. Claims 31-33 depend from claims 25, 22, 6, 4 and 4. Claim 5 discloses that the tail defines a profile that is larger than the distal portion of the body, and claim 22 requires that the tail includes a broadly wound most proximal coil that has a diameter greater than the diameter of the coils of the body of the device. The stents of the Hussein reference do not include a tail made of a coil that is larger than the coils making up the main part of the device, nor do any of the devices disclosed in Neuss, Barnhart or Whalen. A tail made of such a large coil is therefore not obvious in view of any combination of these references, and the rejection on this basis must be reconsidered and withdrawn.

Claims 38-48 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Neuss and Hussein. The office action states that Hussein provides a method of implanting a device in the myocardium, and Neuss discloses a vessel occlusion device with a proximal portion larger than the distal portion, and that it would have been obvious to combine the two.

However, the office action points to no teaching or suggestion that would lead one to combine these references, or to lead one to believe that they are combinable. Hussein discloses myocardial implants, and Neuss discloses removable or repositionable occlusion devices. As stated above, obviousness cannot be established without some teaching, suggestion or incentive

supporting the combination, and such motivation must be found within the references themselves. The mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggest the desirability of the combination. *Berghauser v. Dann, Comr. Pats.*, 204 U.S.P.Q. 393 (Dist. DC 1979); *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 221 U.S.P.Q. 929 (Fed. Cir. 1984). Citing references which merely indicate that isolated elements and/or features recited in the claims are known is not a sufficient basis for concluding that the combination of claimed elements would have been obvious. *Ex parte Hiyamizu*, 10 U.S.P.Q.2d 1393 (Bd. Pat. App. & Inter. 1988).

The office action has provided no evidence that the devices of Neuss could be substituted for the devices of Hussein and implanted in myocardial tissue. Without such evidence, the rejection on this basis must be reconsidered and withdrawn.

Applicants submit that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721.

Respectfully submitted,

Joyce C. Hersh
Reg. No. 42,890
Attorney for Applicant
KIRKPATRICK & LOCKHART LLP
75 State Street
Boston, MA 02109-1808
Tel: 617-261-3100
Fax: 617-261-3175

Date: July 20, 2004